Promoting Readiness and Ensuring Proper API Reserves of Essential Medicines (PREPARE) Act of 2021

Introduced by Reps. Abigail Spanberger (D-VA-07) and David B. McKinley, P.E. (R-WV-01)

The *Promoting Readiness and Ensuring Proper API Reserves of Essential Medicines* (*PREPARE Act*) would improve the resiliency of the U.S. pharmaceutical supply chain and fight shortages of essential drugs by:

- Requiring the Secretary of the U.S. Department of Health and Human Services to establish and make public a list of essential generic medicines that are medically necessary to have available at all times;
- Creating a national stockpile of API for these essential generic medicines to further bolster U.S. emergency preparedness capacity;
- Establishing a plan to store, track, test, and convert API stored in the reserve into finished dosage form and strengthen U.S. capacity for API production; and
- Cutting red tape that could prevent a manufacturer from ramping up production in an emergency.

BACKGROUND

Active Pharmaceutical Ingredients (APIs) are essential ingredients in the manufacturing of any pharmaceutical product, including the generic drugs that make up 90 percent of all prescriptions filled in the United States. APIs are relatively cheap to make and sell, and as of 2020, about 80 percent of API manufacturers are located outside the United States.

China is the world's largest producer of APIs, and millions of Americans take life-saving drugs that contain APIs made in China, even if the finished drugs themselves are not made in China.

Our dependence on China and other foreign suppliers for essential medicines and the ingredients to make those medicines is a national security risk. Relying on foreign suppliers means the United States is vulnerable to shortages of essential medicines needed to respond to bio-terrorism threats or another global pandemic. For example, the United States can no longer manufacturer penicillin and other generic antibiotics.

Even before the COVID-19 pandemic, shortages of essential medicines undermined routine healthcare in the United States. Physicians and hospitals have struggled to reliably access antibiotics, chemotherapies, and medicines for Alzheimer's, Parkinson's, HIV/AIDS and other diseases.

Section by Section

Section 1: Short Title

Designates that this legislation be referred to as the Promoting Readiness and Ensuring Proper Active Pharmaceutical Ingredient Reserves of Essential Medicines (PREPARE) Act of 2021.

Section 2: Listing of Essential Generic Medicines

Section 2 of the PREPARE Act amends the Public Health Service Act to require the Secretary of the Department of Health and Human Services (HHS) to establish and make public a list of essential generic medicines that are medically necessary to have available at all times.

The legislation specifies that the initial list shall be composed of those generic medicines included on the list of essential medicines the Food and Drug Administration (FDA) published on October 30, 2020, and requires the Secretary to review and update this list of essential generic medicines on an annual basis based on regular threat assessments conducted in partnership with the Medical Countermeasures Enterprise. This section also requires the Secretary to consider specific populations in establishing the list (including pediatric populations), and provide a rationale for the inclusion (and removal of) essential generic drugs included on the list. The Secretary shall establish a process for external stakeholders to appeal the Secretary's determination to not include a particular essential generic medicine on the list.

Finally, this section establishes a new position within HHS – the Director of the Strategic Active Pharmaceutical Ingredients Reserve – that must have experience relevant to managing the domestic reserve of active pharmaceutical ingredients established in Section 3.

Section 3: Establishment of the Strategic Active Pharmaceutical Ingredient Reserve

Section 3 of the PREPARE Act establishes a new federal entity to identify, purchase, track, transport, manage, store, and convert an emergency supply of active pharmaceutical ingredients (API) for essential generic medicines to further bolster the United States' emergency preparedness response capacity. Designed to supplement the Strategic National Stockpile (SNS), the strategic API reserve will store and manage a supply of API sufficient to manufacture the essential generic medicines on the list established under Section 2 of the PREPARE Act in an amount adequate to serve the needs of patients living in the United States.

Strategic API Reserve Plan: the legislation requires the Secretary of HHS, in partnership with the Assistant Secretary for Preparedness and Response (ASPR), the Director of the Centers for Disease Control and Prevention (CDC), the Commissioner of Food and Drugs (FDA), and the Director of the Biomedical Advanced Research (BARDA) to establish a plan to inform the establishment and maintenance of the strategic API reserve. Such plan will:

- Identify and prioritize those essential generic medicines listed in Section 2 that will be included in the new strategic API reserve, as well as the amounts necessary to cover the projected health care needs for the U.S. population for a year;

- Include a comprehensive assessment of the essential generic medicines included on the list established by Section 2 to identify where each medicines' API is manufactured, and whether the material or finished drug product is manufactured domestically or abroad;
- Review the types of facilities, equipment, and technology necessary to store, track, test, and convert API included in the reserve into finished dosage form, and include an evaluation of capacity and cost associated with acquiring, storing, and managing API;
- Include a comprehensive distribution plan for API held in the reserve and a process for converting API from the reserve into finished dosage form;
- Be updated annually and submitted to applicable Committees in Congress in a manner that does not compromise national security;
- Detail the design, construction, and requirements for establishing and maintaining the reserve;
- Be designed to minimize any potential impact on the importation of API or finished dosage forms of essential generic medicines;
- Strengthen U.S. domestic capacity for API production, storage, and conversion into finished dosage form; and
- Ensure coordination with the Strategic National Stockpile.

The legislation requires the Secretary to account for no less than 25 essential generic medicines in their first annual Strategic API Reserve Plan, prioritizing those needed for immediate emergency response, and to include 25 additional essential generic medicines in the Plan each year thereafter until the full list established in Section 2 is accommodated by the Plan. The legislation also specifies the minimum amount of API required for storage in the Strategic API Reserve, building capacity over a decade.

Finally, this section provides for the Secretary to establish and maintain a Strategic API Reserve, acquire API and key starting materials to store in the Reserve, and distribute materials from the Reserve in accordance with the Strategic API Reserve Plan. This shall be done in a manner that minimizes the vulnerability of the U.S. to shortages or disruptions for essential generic medicines and gives preference to domestic manufacturers and contractors. In carrying out this section, the legislation specifically:

- Provides for the Secretary to consult with the FDA Commissioner, Administrator of the Centers for Medicare and Medicaid Services, ASPR, and the CDC Director;
- Requires the Secretary to prioritize domestic contractors and manufacturers to the extent possible, and to domestic nonprofit and public-private partnerships, as appropriate;
- Ensures geographic diversity of the physical storage of API; and
- Authorizes such sums as necessary to carry out these requirements.

Section 4: Waiver of Certain FDA ANDA Requirements

This section provides a narrow waiver to allow manufacturers that hold FDA approval for an essential generic medicine(s) to utilize API from the Strategic API Reserve established by this legislation in lieu of API from a source listed on the approved application, so long as the manufacturer informs the FDA of a change in its source of API prior to commercial distribution of the drug in a manner determined appropriate by the Secretary.

Section 5: GAO Report

This section requires the Government Accountability Office (GAO) to prepare and submit a report on domestic API capacity within 1.5 years of the PREPARE Act becoming law.